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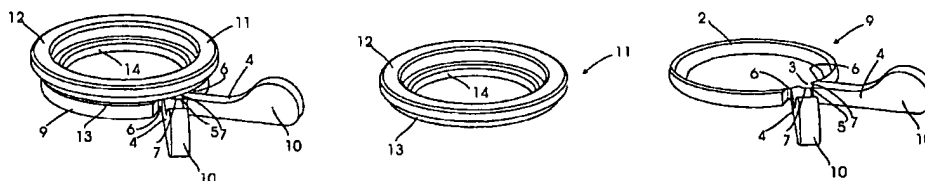
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(54) Title: A CLAMP FOR DETACHABLE MOUNTING OF A DEVICE ON A PREFERABLY ANNULAR IMPLANT BY MEANS OF A CLAMPING FORCE



(57) Abstract: A clamp serving for detachably mounting a device (18, 19, 20) on e.g. an ostomy pouch (19) or a coupling part (18) on e.g. an ostomy pouch (19) on a preferably annular implant (15) by means of a clamping force. The clamp is of the kind that has two arms (4) each defining a jaw (7) and a handle (8, 10), a hinge (5) designed between the jaws (7) and the handle (8, 10), which e.g. is an integral hinge, and a clamp spring (2) for clamping the jaws (7) to each other. The clamp spring (2) is designed as a spring ring (2) with a cross slit (3) and serving for clamping around the implant (15) in mounted state by means of said clamping force. The jaws (7) are pivotally connected with the spring ring (2). The clamp can form an integrated part of an ostomy pouch and be placed inside this pouch. The clamp is easy and inexpensive to manufacture and can be manipulated by a person with weak finger strength.

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**A clamp for detachable mounting of a device on a preferably annular implant by means of a clamping force**

5 The invention relates to a clamp for detachably mounting a device on a preferably annular implant by means of a clamping force and of the kind that has two arms each defining a jaw and a handle, a hinge designed in the area between the jaws and the handle for pivotally connecting the arms to each other, and a clamp spring for clamping the jaws to each other.

10

Known devices such as e.g. an ostomy pouch can in some designs have coupling parts for coupling the pouch to corresponding couplings parts on an adhesive face around a stoma. The coupling means on the ostomy pouch can be used for coupling  
15 with an annular implant but are not directly designed for this exact purpose. Therefore, the ostomy pouch cannot always be fastened securely to the implant and can in these cases therefore not form a completely tight sealing with this implant. For example, small difference in diameter can be the  
20 cause of a loose coupling which cannot ensure effectively against leakage.

The inventors of the present invention have solved a considerable part of these problems with the invention  
25 according to the Danish patent application No. PA 2000 00025 which relates to an ostomy pouch joined with a coupling making it possible to effectively fasten e.g. an ostomy pouch to a mainly annular implant.

30 As an advantageous alternative to this invention, the inventors have not developed the present invention, the object of which is to provide a clamp of the kind mentioned in the opening paragraph, that can be made to fasten a device to an implant in a simple and plain way without causing  
35 inconvenience to a patient with an implanted implant.

A second object of the invention is to provide a clamp that can be manipulated by a person having little finger strength.

5 A third object of the invention is to provide a clamp that can be cast in one piece in one single process in a simple way.

A fourth object of the invention is to provide a clamp that is provided with a sealing ring for sealing with the implant.

10 The novel and unique features according to the invention, whereby this is achieved, is the fact that the clamp spring is designed as a spring ring with a cross slit and is serving for fastening the device to the implant in mounted state, and that the jaws are pivotally connected with the spring ring.

15 By pressing the finger handle of the arms in towards each other by means of the finger tips, the jaws of the arms are opened, the jaws thereby open and prestress the spring ring elastically.

20 The thus elastically deformed, open spring ring can now easily and simply be guided in over the implant upon mounting. By subsequently letting go of the finger handles, the spring ring will return at least partially to a position in which it will  
25 exert the desired clamping force on the implant.

In this simple way, the clamp and a possible associated device, such as e.g. an ostomy pouch which can be completely or partly integrated with the clamp, are mounted quickly and  
30 easily on e.g. an annular implant. The clamp fits closely and tightly around the implant without use of locking means which are difficult to manipulate especially for a person having weak fingers and are difficult to see in details for a person having failing eyesight.

35

In a preferred embodiment, the spring ring and the arms of the clamp can be made in one piece, the jaws and the spring ring then being pivotally connected to each other via two integral hinges, and the hinge of the arms being a second integral  
5 hinge. Thereby, a clamp is obtained which is extremely inexpensive and functioning reliably.

This embodiment of the clamp can expediently be made of a plastic such as polypropylene, nylon or similar relatively  
10 hard, dimensionally stable, inexpensive, high-molecular polymers that are elastically deformable.

A clamp designed with integral hinges in one piece with the spring ring can easily be injection-moulded. Therefore, the  
15 components of the clamp do not have to be joined by separate parts by e.g. welding or bonding. Thereby, price-raising finishing is avoided. Furthermore, the free movement of the integral hinges is enabled and not hindered by neither adhesive residues or welding burrs. Furthermore, there is no  
20 risk of the clamp breaking by accident at weakened or exposed points of joining when the clamp is spring loaded during mounting or dismounting.

By designing the spring ring with an inside diameter that  
25 corresponds to or is smaller than the largest outside diameter of the annular implant in the rest position of the spring ring, it is ensured that the clamp always clamps securely around the implant. The spring ring can actually have any cross section that can engage with and be received by a groove  
30 designed correspondingly in the implant but in an especially preferred embodiment, the cross section can be mainly rectangular in order to thereby eliminate the risk of the ring buckling during the mounting operation.

35 However, the spring ring does not necessarily have to be designed to fit completely or partly in a corresponding

groove. Instead, it can quite simply clamp around a cylindrical part of the implant.

5 If the radial thickness of the spring ring is smallest in the area of the slit and gradually increasing towards the diametrically opposite area of the spring ring, the ring can maintain a mainly circular configuration in all positions and affect the implant with the same clamping power along the entire periphery.

10 The clamp can advantageously be provided with a sealing ring serving for forming sealing between the implant and the device and advantageously made of an elastomer which for example can be a rubber.

15 If at least a part of the sealing ring is extending along the radial inside face of the spring ring, the sealing ring forms an elastic bridge across the cross slit of the spring ring so that an effective clamping effect between the spring ring and  
20 the implant is also obtained in this area.

The clamp can advantageously be used for coupling the implant to e.g. a commercially available ostomy pouch designed with a groove around the ostomy opening for receiving the clamp.

25 Furthermore, the spring ring can be cast together with the sealing ring in a casting process where the sealing ring is made to adhere to at least a part of the spring ring for example the radial inside face of the spring ring. Thereby, it  
30 is obtained that the two parts are effectively and securely joined to each other in a simple and inexpensive way.

35 If the arms of the clamp are extending outwards mainly on the same plane as the spring ring, the clamp will take up the least possible room. The arms are easy to manipulate by means of the handles which can be designed with different sizes

depending on the actual needs so that e.g. a person having little finger strength can find a rest for his finger tips.

5 The two first integral hinges can be at the inside face of the spring ring and form part of the spring ring on either side of the cross slit. Thereby, the structure becomes compact.

10 In a preferred embodiment, each of the jaws can furthermore have a length of between  $\frac{1}{4}$  and 2, preferably between  $\frac{1}{4}$  and  $1\frac{1}{4}$  times and especially between  $\frac{3}{4}$  and  $1\frac{1}{4}$  times the radial thickness of the spring ring. These dimensions are such that the spring ring can open sufficiently upon mounting to allow it to be guided in over the implant without difficulty and then clamp securely and firmly around this implant.

15 Further, the arms can be between  $1\frac{1}{4}$  and 10, preferably between 2 and 7 and especially between 2 and 5 times the length of the jaws. Thereby, the clamp is given a ration of transmission which advantageously can be used to open a strong and  
20 effectively functioning spring ring with even modest finger strength.

25 Stomy-operated patients have a great and so far unmet need to easily and when required be able to close or block an ostomy aperture. This possibility now also exists to stomy-operated patients using the annular implants known from the inventors' patent no. US 6,017,355 and patent applications no. DK/PA 1999 01026 and DK/PA 2000 00521, as the clamp advantageously can be designed with a cover over the opening of the spring ring.  
30 When the stomy-operated patient mounts the clamp with cover over the implant, the patient obtains both comfort and freedom of movement.

35 In an advantageous embodiment, the clamp according to the invention can be placed inside an ostomy pouch in such a way

that the spring ring is fastened along the edge of the ostomy aperture of the pouch.

5 In an especially advantageous way, an edge area at the ostomy aperture of the ostomy pouch can be bent in over and fastened along the radial inside face of the spring ring. Thereby, the edge area will function as the sealing mentioned above upon mounting of the ostomy pouch on the annular implant.

10 Such a fabricated ostomy pouch with integrated clamp is easy and inexpensive to manufacture by means of known techniques. Further, the pouch is simple and quick to mount on and dismount the implant.

15 The invention will be explained in greater detail below, describing only exemplary embodiments with reference to the drawing, in which

Fig. 1 is a perspective view of an especially simple  
20 embodiment of a clamp according to the invention,

Fig. 2 is a perspective view of a second embodiment of a clamp according the invention,

25 Fig. 3 is a perspective view of the second embodiment of the invention mounted with a sealing ring and an exploded view of this second embodiment,

Fig. 4 shows the same view in fig. 3 during mounting on an  
30 implant,

Fig. 5 is a sectional view taken along the line V-V of fig. 4,

Fig. 6 is a perspective view of the first embodiment of the  
35 clamp mounted inside an ostomy pouch and fastened in the ostomy aperture of this pouch,

Fig. 7 is a perspective view of a third embodiment with a lock clamp between the free ends of the arms,

- 5 Fig. 8 shows the same view in fig. 7 but with the lock clamp in its unloaded state,

Fig. 9 is a perspective view of a clamp with a cover, and

- 10 Fig. 10 is a sectional view taken along the line X-X of fig. 9.

The invention is described in the following on the assumption that the clamp according to the invention is used for an  
15 ostomy pouch on an implant. Within the scope of the invention, the clamp can however be used with just as great advantage for many other devices, of which examples are wigs for mounting on a bald pate, tubes for e.g. rinsing of a faeces reservoir of a patient with implant made in connection with a stoma, or in  
20 general for tubes which are to be clamped around another part.

The simple clamp 1 in fig. 1 is made of a spring ring 2 passing into two projecting arms 4 at a cross slit 3, said arms are partly interconnected by a integral hinge 5, partly  
25 connected with the spring ring via integral hinges 6. The arm are designed with jaws 7 and handles 8 serving as rest to fingers when the clamp 1 is to be mounted on an annular implant or taken off this implant. When the handle 8 of the clamp 1 is actuated with a pressing force in the direction of  
30 the arrows, that is in a direction towards each other, the spring ring 2 is opened to a size that is sufficiently great for the spring ring to be guided in over an implant (not shown). When the handles are released again, the spring ring will return to a mounted position in which the spring ring is  
35 clamping around the implant with its spring power.



The clamp 9 in fig. 2 corresponds mainly to the embodiment shown in fig. 1, and like parts are therefore referenced similarly. The only difference is that the handles 10 are designed with a greater contact face to conveniently be able to press the handles together with the fingers.

In the exploded view in fig. 3, the clamp 9 is seen with a sealing ring 11. The sealing ring has an outer part 12 and an inner part 13. The outer part 12 has a greater outside diameter than the inner part 13, the outside diameter of which corresponds to the inside diameter of the spring ring 1. The inner part 13 is embedded along the inside periphery of the spring ring 1 and spans the cross slit 3. Along an inside periphery area of the inner part, the sealing ring has a circumferential projection 14 serving for engaging with a groove in the implant 15 in fig. 4. The circumferential projection 14 of the inner part therefore has a thickness that mainly corresponds to the height and depth of this groove. This appears more clearly from the cross section of the clamp 9 mounted on the implant 15 in fig. 5.

In the cases shown in figs. 3, 4, and 5, the sealing ring is made of an elastic material, such as rubber, which easily yields to the movement of the spring ring during mounting and dismounting. The sealing ring 11 will advantageously settle as a tight, elastic sealing between the implant and the spring ring.

Fig. 5 shows, taken along the line V-V of fig. 4, the clamp 9 with a sealing ring 11, mounted on the coupling part 18 of a commercial ostomy pouch 19. The outer part 12 is designed with a radial thickness and a diameter respectively that are suited for this part to be pressed into the groove 17 on the coupling part 18 of the ostomy pouch 19. Such a commercially available ostomy pouch 19 is marketed by e.g. Coloplast Group A/S, DK-3050 Humlebæk, Denmark and Dansac A/S, Lille Kongevej, DK-3480

Fredensborg, Denmark. In the example shown, the radial thickness is relatively great. For some purposes, the width of the groove 17 of the coupling part 18 is small, and the outer part 12 is then designed with correspondingly small dimensions.

In the exploded view in fig. 4, the clamp 9 of fig. 3 with an embedded sealing ring 11 is shown as illustration example mounted on the implant 15 known from the Danish patent application no. DK/PA 2000 00521. The circumferential projection 14 is received in the groove 16 of the implant 15. The implant 15 is not part of the scope of the present invention and will therefore not be mentioned any further here.

In fig. 6, the clamp 1 is placed inside an ostomy pouch 20 at the ostomy aperture 21 of this pouch. A part of the pouch material at the opening 21 is bent in over the top of the spring ring 2 and down along its inside face where the pouch material is securely fastened and is serving as an expedient sealing. In this case, the ostomy pouch is made of a flexible plastic such as e.g. polyethylene which can resist great tensile stresses without breaking or weakening.

Such a material is especially expedient as it can yield to the different shapes of the spring ring when the ring's diameter is increased during mounting and dismounting of the clamp.

In fig. 6, the arms of the clamp 1 are positioned in such a way that they mainly face upwards when the ostomy pouch is in use. This position makes it easy for the patient to get hold of the handles of the arms. In case of the pouch material not forming part of the sealing, the clamp can alternatively be welded or bonded to the inside of the ostomy pouch along a free outer side and subsequently be provided with a sealing ring of an elastomeric material along the inside periphery.

Combinations where the sealing ring is consisting of both pouch material and an extra rubber sealing is also possible within the scope of the invention.

- 5 Figs. 7 and 8 show a clamp 22 with a bow 23 having a length greater than the largest possible distance between the handles 8 of the arms 4 and furthermore sufficiently great for the bow to press the arms 4 so far apart that the spring ring 2 can be opened sufficiently to be guided down over the implant.

10

Fig. 7 shows the open spring ring 2 with the bow 23 pressed down between the arms in the direction of the arrow. In fig. 8, the bow 23 is drawn back in the direction of the arrow whereby the spring ring 2 is placed in the rest position.

15

Just as the embodiments in figs. 1 and 2, this embodiment can be mounted inside and be integral with an ostomy pouch and just as the clamps 1 and 9, it can be provided with a sealing ring 12.

20

The clamps 22 are very useful to a person who, due to weak finger strength or reduced sense of touch in the finger tips, has trouble in overcoming the reaction of the spring power of the spring ring when the person is to press the handles 8 together with the fingers upon mounting of the clamp.

25

In fig. 9, the clamp 1 is shown in an embodiment where the aperture is covered with a cover 24. A clamp arranged in such a way will give a unique possibility of closing the stoma/the free discharge of the implant into the surroundings and will give the user a new and hitherto unknown freedom of movement to e.g. go in for sports without at the same time being handicapped by a full ostomy pouch.

30

- 35 Fig. 10 is a sectional view taken along the line X-X of fig. 9. In the case shown, the clamp is provided with a sealing

ring 25 along the inside periphery of the spring ring. The sealing ring is serving for ensuring that the clamp can be clamped optimally on an implant. To further ensure this, the sealing ring 25 has a circumferential projection 26. The cover  
5 can e.g. be made of a resilient, elastic material, or can alternatively be a lever lid or possibly a screw cap over the opening of the spring ring.

## Patent claims

1. A clamp (1,9,22) for detachably mounting a device (18,19,20) on a preferably annular implant (15) by means of a clamping power and of the kind that has two arms (4) each defining a jaw (7) and a handle (8,10), a hinge (5) made in the area between the jaws (7) and the handle (8,10) for pivotally connecting the arms (4) to each other, and a clamp spring (2) for clamping the jaws (7) towards each other, **characterised** in that the clamp spring (2) is made as a spring ring (2) with a cross slit (3) and serving for clamping the device on the implant (15) with said clamping power in mounted state, and that the jaws (7) are pivotally connected with the spring ring (2).
2. A clamp (1,9,22) according to claim 1, **characterised** in that the spring ring (2) and arms (4) of the clamp (1,9,22) are made in one piece, that the jaws (7) and the spring ring (2) are pivotally connected with each other via the integral hinges (6), and that the hinge (5) is a second integral hinge (5).
3. A clamp (1,9,22) according to claim 1 or 2, **characterised** in that the spring ring (2) is cast in one piece of plastic.
4. A clamp (1,9,22) according to any of the claims 1, 2 or 3, **characterised** in that the spring ring (2), in its rest position, has an inside diameter corresponding to or slightly smaller than the greatest outside diameter of the annular implant (15).
5. A clamp (1,9,22) according to any of the claims 1 - 4, **characterised** in that the spring ring (2) has a mainly rectangular cross section.

6. A clamp (1,9,22) according to any of the claims 1 - 5,  
**characterised** in that the radial thickness of the spring  
ring (2) is smallest in the area of the cross slit (3),  
5 and that this thickness is gradually increasing towards  
the diametrically opposite area of the spring ring (2).
7. A clamp (1,9,22) according to any of the claims 1 - 6,  
**characterised** in that the clamp (1,9,22) is provided with  
10 a sealing ring (11) for forming a sealing between the  
implant (15) and the device (18,19,20).
8. A clamp (1,9,22) according to claim 7, **characterised** in  
that the sealing ring (11) is made of an elastic  
15 material, and that a part of the sealing ring (11) is  
extending along the radial inside face of the spring ring  
(2).
9. A clamp (1,9,22) according to any of the claims 7 or 8,  
20 **characterised** in that the spring ring (2) and the sealing  
ring (11) are cast together.
10. A clamp (1,9,22) according to any of the claims 1 - 6,  
**characterised** in that the arms (4) of the spring ring  
25 (1,9,22) are extending outwards mainly on the same plane  
as the spring ring (2).
11. A clamp (1,9,22) according to any of the claims 1 - 10,  
**characterised** in that the two first integral hinges (6)  
30 are located at the inside face of the spring ring (2),  
and that each jaw (7) has a length of between  $\frac{1}{4}$  and 2,  
preferably between  $\frac{1}{4}$  and  $1\frac{1}{4}$ , and especially between  $\frac{1}{4}$  and  
 $1\frac{1}{4}$  times the radial thickness of the spring ring (2).
- 35 12. A clamp (1,9,22) according to any of the claims 1 - 10,  
**characterised** in that the arms (4) are between  $1\frac{1}{2}$  and 10,

preferably between 2 and 7, and especially between 3 and 5 times the length of the jaws (7).

- 5 13. A clamp (1,9,22) according to any of the claims 1 - 10, **characterised** in that the clamp (1,9,22) is made with a cover (24) over the opening of the spring ring.
- 10 14. A clamp (1,9,22) according to any of the claims 1 - 10 and where the device (18,19,20) is an ostomy pouch (20), **characterised** in that the clamp (1,9,22) is placed inside the ostomy pouch (20), and that the spring ring (2) is fastened along the edge of the ostomy aperture (21) of this pouch.
- 15 15. A clamp (1,9,22) according to claim 14, **characterised** in that an edge area at the ostomy aperture (21) of the ostomy pouch (20) is fastened along the radial inside face of the spring ring (2).

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/DK 01/00522

## A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61F 5/448, F16B 2/22

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61F, F16B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPODOC, MEDLINE

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

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A	US 5322523 A (OLSEN), 21 June 1994 (21.06.94), figures 12-13 --	1-15
A	US 5364379 A (OZENNE ET AL), 15 November 1994 (15.11.94), figures 13-14, abstract --	1-15
A	US 5843053 A (STEER), 1 December 1998 (01.12.98), figure 8 -----	1-15

☐ Further documents are listed in the continuation of Box C.☒ See patent family annex.

\* Special categories of cited documents:

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# INTERNATIONAL SEARCH REPORT

Information on patent family members

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				JP	10075974	A	24/03/98	
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The following items listed below are being filed herewith with the USPTO on February 6, 2004

Express Mail No. <b>EV 346 810 467 US</b>		
Attorney Docket No.	Appln. Serial No./ Patent No.	Items - Documents filed on <b>February 6, 2004</b>
81421-4037	<b>TBA</b>	Utility Patent Application Transmittal (PTO/SB/05); Specification 23 pages including 38 claims; Formal Drawings 18 pages (1-26); Application Fee Sheet (in duplicate); Copy of Inventors' Declaration (2 pages) (unexecuted); Information Disclosure Statement, PTO 1449, 4 refs.

*Please acknowledge receipt of these items as received by returning the enclosed postcards with the date of receipt of February 6, 2004*

NY:840388.2